B 2

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,264	02/27/2002	Spiros Fotinos	1581/130	2006

2101 7590 09/23/2004

BROMBERG & SUNSTEIN LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,264	FOTINOS, SPIROS	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,19 and 21-32* is/are pending in the application.

4a) Of the above claim(s) *19,21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 23-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/28/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on May 28, 2004 have been received and entered into the application.

Action Summary

The rejection of claims 1-3 and 6-13 of record under 35 U.S.C. 102(b) as being anticipated by Fischel-Ghodsian (U.S. Patent No. 5,070,704) of record is hereby expressly withdrawn in view of Applicants' amendment.

The rejection of claims 23 and 24 of record under 35 U.S.C. 103(a) as being unpatentable over Fischel-Ghodsian (U.S. Patent No. 5,070,704) of record is hereby expressly withdrawn in view of Applicants' amendment.

The rejection of claims 4 and 5 of record under 35 U.S.C. 103(a) as being unpatentable over Fischel-Ghodsian (U.S. Patent No. 5,070,704) as applied to claims 1-3, 6-13, 23 and 24 above, and further in view of Fujita et al. (U.S.Patent No. 5,928,661) and Sweeney (GB 2260494A), all of record is hereby expressly withdrawn in view of Applicants' amendment.

Applicants' amendment necessitated the new rejection presented in this Office action.

Claim Rejections - 35 USC § 102

Claims 1-3 and 6-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischel-Ghodsian (U.S. Patent No. 5,070,704) of record.

Fischel-Ghodsian teaches controlled device comprising an adhesive layer for adhering to skin or a surface comprising 1) reservoir layer which incorporates an active compound such as air freshener, various fragrances, air fresheners, insecticides, vapor emitting compounds, naturally occurring essential oils, perfumes, 2) a diffusion rate limiting membrane layer, 3) an impermeable backing layer (adjacent to the reservoir layer) that provides a barrier to the diffusion of the active compound and a peeling layer. (abstract, column 3, lines 15-32, column 2, lines 55-67, column 3, lines 15-52, column 4, lines 22-35, lines 64-colunn 5, line 58, column 6, lines 10-16, claims 1-3). Fischel-Ghodsian teaches that the reservoir layer of the laminate is in the form of a gelled mixture (an oil and polymer) and a liquid when the active compound is an oil soluble compound. (column 4, lines 64-68). Fischel-Ghodsian teaches the active compound of choice may be incorporated into the reservoir layer polymer by conventional methods known in the art for incorporating polymeric additives and the active compound of choice may be incorporated in the system utilized to produce the polymer, and the active compound and the polymer form a two phase system in which particulates of the compound are dispersed throughout the polymer. (column 4, lines 43-65). Fischel-

Ghodsian teaches that above composition can deliver vapors or liquids for a period of from 1 to 72 hours. (column 2, lines 63-66).

It is noted that Applicants' limitation of a "patch" reads on the prior art since the prior teaches all the components of the "patch" set forth in Applicant's claim 1 and does not represent a patentable limitation since such fails to impart any physical limitation to the same composition "device" comprising same active components. Further, Applicant's recitation in claims 11-13 of an effect does not represent a patentable limitation since such fails to impart any physical limitation to the composition and it is inherent effect of the prior composition since it is drawn to the same active agent (i.e. a volatile active agent). Moreover, the cited prior art encompasses Applicants' limitation of "**adhesive between** adjacent sides of the solid layer and the barrier layer" since the reservoir layer taught by Fischel-Ghodsian that the active compound and the **polymer** form a two phase system in which particulates of the compound are dispersed throughout the polymer and that "adhesive" utilized by the Applicants in specification page 9, lines 14-15 are in fact the same polymers comprising active agent (reservoir layer) taught by the prior art.

Claim Rejections - 35 USC § 103

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischel-Ghodsian (U.S. Patent No. 5,070,704) as applied to claims 1-3, 6-13, 23 and 24

above, and further in view of Fujita et al. (U.S.Patent No. 5,928,661) and Sweeney (GB 2260494A), all of record.

Fischel-Ghodsian applied as before and additional teachings as follow.

Fischel-Ghodsian teaches that in addition to gelling agents, reservoir may include other materials such as stabilizers. (column 5, lines 20-21).

Fischel-Ghodsian does not teach the specific wax of ozokerities and sodium stearate in the solid layer.

Fujita et al. teaches controlled release composition comprising volatile plasticizer such as ozokerite. (column 1, line 65-column 2, line 11, column 3, lines 20-28, column 3, line 51- column 4, line 5, particularly, column 4, line 2). Fujita et al. teach that the plasticizer facilitates mixing and kneading the composition. (column 3, line 51- column 4, line 5).

Sweeney teaches fragrant controlled release composition for use as an air freshener comprising a volatile fragrant compound and a binding agent such as sodium stearate. (abstract, page 2, lines 4-7, page 3, lines 8-12, page 4, lines 7-10, page 8, line 14).

It would have been obvious to one of ordinary skill in the art to incorporate ozokerites and sodium stearate in the reservoir layer (solid layer) of Fischel-Ghodsian composition because Fischel-Ghodisan teaches that the reservoir layer may include other materials and because ozokerite facilitates mixing and kneading of the composition. Further sodium stearate is routinely used in the air freshener composition in controlled release form of volatile fragrant composition as a binding agent. One of

ordinary skill in the art would have been motivated to incorporate ozokerite and sodium stearte into Fischel-Ghodisan's reservoir layer and make such modification because they are drawn to same technical fields (constituted with controlled release air freshener related device and well known additives (e.g. plasticizer, binders), and pertinent to the problem which applicant concerned about. MPEP 2141.01(a).

Claims 24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischel-Ghodsian (U.S. Patent No. 5,070,704) of record.

Fischel-Ghodsian applied as before and additional teachings as follow.

Fischel-Ghodsian teaches the diffusion rate membrane is then placed adjacent to the reservoir layer. (column 9, lines 40-45). Fischel-Ghodsian teaches the diffusion rate limiting membrane layer can be selected from any one of the polymers known in the art including polypropylene, cellulose acetate, cellulose nitrate and polytetrafluorotheylene. (column 5, lines 22-34).

Fischel-Ghodsian does not expressly teach the sealed pouch of the patch and a non-woven fabric having at least cellulose fibers and resin.

It would have been obvious to one of ordinary skill in the art to provide sealed pouch enclosing the device taught by Fischel-Ghodsian since it is routine manufacturing process for dispensing a patch or device to store or deliver the product as sterile as possible with its original manufactured condition in order to avoid unwanted contamination by any means. One of ordinary skill in the art would have been

motivated modify the teaching of Fischel-Ghodsian and to provide sealed pouch enclosing the device to achieve sterility of the patch formulated by Fischel-Ghodsian.

Applicants' limitation of a non-woven fabric having at least cellulose fibers and resin is obvious since Fischel-Ghodsian teaches the diffusion rate limiting membrane layer can be selected from any one of the polymers known in the art (non-woven fiber) including polypropylene, cellulose acetate, cellulose nitrate and polytetrafluorotheylene. One would have been motivated to use any one of non-woven fiber including cellulose fibers and resin without surprising and unexpected result.

Claims 23 and 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischel-Ghodsian (U.S. Patent No. 5,070,704) as applied to claims 1-3 and 6-13 above, and further in view of Fujita et al. (U.S.Patent No. 5,928,661) and Sweeney (GB 2260494A), all of record.

Fischel-Ghodsian applied as before and additional teachings as follow.

Fischel-Ghodsian teaches the polymer-perfume gel was spread onto the impermeable membrane layer forming the reservoir layer of the laminate and the diffusion rate membrane is then placed adjacent to the reservoir layer. (column 9, lines 40-45). Fischel-Ghodsian teaches the diffusion rate limiting membrane layer can be selected from any one of the polymers known in the art including polypropylene, cellulose acetate, cellulose nitrate and polytetrafluorotheylene. (column 5, lines 22-34).

Fischel-Ghodsian does not expressly teach the process of making solid layer having been made in order by applying liquid mixture onto the breathable layer of the

device and the sealed pouch of the patch and the specific wax of ozokerities and sodium stearate in the solid layer and a non-woven fabric having at least cellulose fibers and resin.

Fujita et al. teaches controlled release composition comprising volatile plasticizer such as ozokerite. (column 1, line 65-column 2, line 11, column 3, lines 20-28, column 3, line 51- column 4, line 5, particularly, column 4, line 2). Fujita et al. teach that the plasticizer facilitates mixing and kneading the composition. (column 3, line 51- column 4, line 5).

Sweeney teaches fragrant controlled release composition for use as an air freshener comprising a volatile fragrant compound and a binding agent such as sodium stearate. (abstract, page 2, lines 4-7,, page 3, lines 8-12, page 4, lines 7-10, page 8, line 14).

The process of making solid layer of the device by applying a liquid mixture on to the breathable layer is obvious because Fischel-Ghodsian teaches that the gel was spread on to form the reservoir and that diffusion rate limiting membrane was then placed adjacent of the reservoir layer. One of ordinary skill in the art would have been motivated modify the process of Fischel-Ghodsian in any order for the convenience and individual manufacturing preference since the diffusion membrane layer and the reservoir layer is ultimately placed adjacent to each other. It would have been obvious to one of ordinary skill in the art to incorporate ozokerites and sodium stearate in the reservoir layer (solid layer) of Fischel-Ghodsian composition because Fischel-Ghodisan

teaches that the reservoir layer may include other materials and because ozokerite facilitates mixing and kneading of the composition. Further, sodium stearate is routinely used in the air freshener composition in controlled release form of volatile fragrant composition as a binding agent. One of ordinary skill in the art would have been motivated to incorporate ozokerite and sodium stearate into Fischel-Ghodisan's reservoir layer and make such modification because they are drawn to same technical fields (constituted with controlled release air freshener related device and well known additives (e.g. plasticizer, binders), and pertinent to the problem which applicant concerned about. MPEP 2141.01(a). Applicants' limitation of a non-woven fabric having at least cellulose fibers and resin is obvious since Fischel-Ghodsian teaches the diffusion rate limiting membrane layer can be selected from any one of the polymers known in the art (non-woven fiber) including polypropylene, cellulose acetate, cellulose nitrate and polytetrafluorotheylene. One would have been motivated to use any one of non-woven fiber including cellulose fibers and resin without surprising and unexpected result.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed May 28, 2004 have been fully considered but they are not persuasive. Applicants essentially argue that Fischel-Ghodsian fails to teach or suggest the element of "adhesive between adjacent sides of the solid layer and the barrier layer" as required by the claims. This is not persuasive because Fischel-Ghodsian teaches the active compound of choice may be incorporated into the reservoir layer polymer by conventional methods known in the art for incorporating polymeric additives and the active compound of choice may be incorporated in the system utilized into produce the polymer itself, and the active compound an the polymer form a two phase system in which particulates of the compound are dispersed throughout the polymer. Therefore, this teaching encompasses Applicants' limitiation of "**adhesive between** adjacent sides of the solid layer and the barrier layer" since the reservoir layer taught by Fischel-Ghodsian comprisies the active compound an the **polymer** form a two phase system in which particulates of the compound are dispersed **throughout** the polymer and that "adhesive" utilized by the Applicants in specification page 9, lines 14-15 are in fact the same polymers comprising active agent (reservoir layer) taught by the prior art. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
September 14, 2004